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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,853	06/24/2003	Yung-Nien Chang	4-31401A	9278

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EXAMINER

LONG, SCOTT

ART UNIT PAPER NUMBER

1633

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/602,853	Applicant(s) CHANG ET AL.	
	Examiner Scott D. Long	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                    |                                                                             |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____                                                |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>13 sheets</u> .                                                           | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Status***

Claims 38-96 are pending.

### ***Election/Restrictions***

The election of species directed to (A) a viral enhancer as the tissue specific enhancer, (B) an alpha-fetoprotein promoter as the tissue specific promoter, (C) E1a as the transcription factor, and (D) thymidine kinase as the coding sequence that was received on 27 April 2006 is acknowledged. Upon search and consideration, and in light of the restriction requirement for parent application 08/974391, the restriction among different species is hereby withdrawn.

### ***Information Disclosure Statement***

The Information Disclosure Statement (IDS) filed on 24 June 2003 is in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statement.

### ***Priority***

This application appears to be a division of U.S. Patent No. 6628762 B1, filed 19 November 1997. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an

earlier or parent application is known as a divisional application or "division." The divisional application should set forth the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application.

The instant application has been granted the benefit date, 28 November 1994, from the application 08/348258 (abandoned).

### ***Specification***

The Specification claims priority to application 08/974391; this application has been issued as a U.S. patent (US 6628762 B1). This information should be updated in the Specification.

### **Claim Objections**

Claim 38 is objected to because of the following informalities: the phrase "E1 a" is a typo. Appropriate correction is required.

Claim 44 is objected to because of the following informalities: the phrase "so that replication said cell" is a grammar error. Appropriate correction is required.

Claim 51 is objected to because of the following informalities: the phrase "Inscriptional" is a typo. Appropriate correction is required.

Claims 84 and 90 are objected to because of the following informalities: the phrase "turn or-specific" is a typo. Appropriate correction is required.

Claim 86 is objected to because of the following informalities: the phrase "transcript ion al" is a typo. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 is directed to producing a virion, yet the method step recovers a "vector." The body of the method claim is inconsistent with the preamble. Therefore the phrase is vague and indefinite.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38-96 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-18 and 20 of U.S. Patent No. 5,998,205. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 12-18 and 20 of the cited patent are directed to an isolated cell containing a tissue-specific replication-conditional adenovirus virion and methods of producing said adenovirus virion. Claims 38-96 of instant application are directed to a virion comprising the adenoviral vector of the cited patent, cells comprising the virion, and method of producing said virion. The instantly claimed virion is fully disclosed in the specification of the cited patent. For example, claim 12 of the cited patent refers to an isolated cell containing an adenovirus virion and claim 18 refers to methods of producing said adenovirus virion. Furthermore, in the specification of the cited patent, virions are produced and recovered by inventors and are therefore possessed by inventors, "In further embodiments, a method is provided for producing a replication-conditional vector or virion comprising the steps of culturing the producer cell line described above and recovering the vector or virion from the cells" (column 5, lines 27-30).

Accordingly, instant claims and the claims of the cited patent are obvious variants. Therefore, the inventions as claimed are co-extensive.

No Claims Allowed.


### Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave Nguyen** can be reached on **571-272-0731**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long  
Art Unit 1633

  
**Q. JANICE LI, M.D.**  
**PRIMARY EXAMINER**